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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/872,250 | 06/01/2001 | Gary S. Grubb | AM100058 | 4735 |

35139 7590 04/22/2005

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| EXAMINER |
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HUI, SAN MING R

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,250

Applicant(s)

GRUBB, GARY S.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 23, 2004 has been entered.

Claims 1-11 are pending.

The instant claims are directed to a kit that comprising multiple packs of oral contraceptives that have different dosage or amount of estrogens. One pack contains more estrogen than the other pack, wherein the less estrogen pack contains no more than 20mcg of estrogen, regardless of how it is arranged or used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Endrikat et al., Hodgen et al. (US Patent 5,552,394) and Katzung, Endrikat et al. in view of Katzung are of record.

Endrikat et al. teaches oral contraceptives with 30mcg Ethinylestradiol has less breakthrough bleeding than that with 20mcg Ethinylestradiol in the first three cycles. Endrikat also teaches that the patterns of the breakthrough pain as highest in the first cycle was due to the fact that the adaptation of the endometrium to the exogenous hormones takes some time (See page 136, col. 1, last paragraph).

Hodgen et al. teaches a method of reducing breakthrough bleeding in the menstrual cycles except for the first cycle employing ultra-low dose of Ethinylestradiol. Hodgen et al. teaches the dose of Ethinylestradiol as 3-35 mcg (See for example the abstract, claims 1-12).

The primary references do not expressly teach the combination of the oral contraceptives packs together in a kit. The primary references do not expressly teach all of the herein claimed progestins.

Katzung teaches the various progestins herein claimed as useful in oral contraceptive.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the oral contraceptives packs of 30mcg and 20mcg of Ethinylestradiol together in a kit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ various progestin herein claimed into the oral contraceptives.

One of ordinary skill in the art would have been motivated to combine the oral contraceptives packs of 30mcg and 20mcg of Ethinylestradiol together in a kit. Hodgen's method of reducing breakthrough bleeding has one drawback, which cannot

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reducing the breakthrough bleeding in the first cycle. Possessing the teachings of Endrikat, one of ordinary skill in the art would reasonably expect to employ a regimen comprising a dose of 30mcg of ethinylestradiol in the first cycle in the Hodgen's method in order to let the endometrium adapt to the exogenous hormones as well as reduce the breakthrough bleeding in the first cycle and thereby improving Hodgen's method.

One of ordinary skill in the art would have been motivated to employ various progestin herein claimed into the oral contraceptives since substituting various known progestin in oral contraceptives would be considered selecting obvious alternatives among known progestins, absent evidence to the contrary.

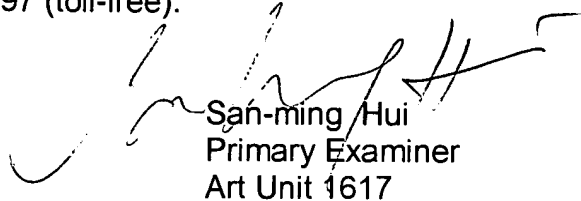
Response to Arguments

Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



San-ming Hui
Primary Examiner
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